Court File No. CV-10-415755-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

STEVEN DALTON DINE

Plaintiff

- and -

BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET MANUFACTURING CORP., BIOMET US RECONSTRUCTION, LLC and BIOMET CANADA INC.

Defendants

Proceedings under the *Class Proceedings Act, 1992,* S.O. 1992, c.6

STATEMENT OF CLAIM

(Notice of Action issued on October 4, 2013)

1. The plaintiff, Steven Dalton Dine claims on his own behalf and on behalf of all members of the Class (defined below):

(a) an order certifying this proceeding as a Class Proceeding and appointing Steven Dalton Dine as representative plaintiff for the Class;

(b) a declaration that the defendants were negligent in the research, design, manufacture, regulatory licensing, sale and post-market monitoring of the Biomet Implants

(c) a declaration that the Biomet Implants are dangerous and not fit for their intended use;

(d) on behalf of the Class, compensatory damages in the amount of $100,000,000.00, or such other sum as this Honourable Court deems just;

(e) special damages in an amount to be determined, including but not limited to past and future loss of income, medical care, screening, diagnosis, examinations, surgical care, and all other medical expenses, including medical expenses for testing, treatment and medical imaging, on behalf of the plaintiffs and the subrogated interest of the Ontario Health Insurance Plan pursuant to sections 30 and 31 of the *Health Insurance Act*, R.S.O. 1990, c. H.6, as amended, and the other provincial and territorial health insurers pursuant to the legislation in the Class members' respective provinces or territories of residence listed in paragraph 68;

(f) punitive damages in the sum of $10,000,000.00;

(g) on behalf of the Family Law Claimants, damages pursuant to the *Family Law Act*, R.S.O. 1990 c. F-3 ("FLA"), or equivalent legislation in other provinces, in the amount of $50,000,000.00 or such other sum as this Honourable Court deems just,

(h) damages equal to the costs of administering the plan of distribution of the recovery in this action;

(i) prejudgment and post-judgment interest in accordance with the *Courts of Justice Act*, as amended, compounded annually;

(j) costs of this action on a substantial indemnity basis, plus HST; and

(k) such other relief as this Honourable Court may deem just.

The Plaintiff and Class

2. The plaintiff, Steven Dalton Dine, ("Steven") is a resident of Kingston, Ontario. As described further below, he was implanted with several Biomet Implants which needed to be removed and replaced.

3. The plaintiff claims on his own behalf and on behalf of the following Class:

(a) all persons who were implanted in Canada with metal-on-metal hip implant systems known as the M2a 38 (the "38"), the M2a Magnum (the "Magnum"), the ReCap Femoral Resurfacing System, and any other Biomet metal-on-metal hip implant system (collectively, the "Biomet Implants"), or any of the Biomet Implant components including heads, stems, tapers, sleeve adaptors and shells (“Implant Patients); and

(b) all other persons who by reason of a personal relationship to an Implant Patient have standing pursuant to s. 61(1) of the *Family Law Act* R.S.O. 1990, c. F.3, or equivalent legislation in other provinces and territories as set out in Schedule "A". (“Family Law Claimants”)

4. The plaintiff also brings this action on behalf of all provincial and territorial health insurers who are entitled to assert a claim for the recovery of the cost of insured services provided to members of the Class, pursuant to provincial legislation.

The Defendants

5. The defendant, Biomet, Inc., is incorporated in the State of Indiana, in the United States and carries on business in the design, manufacturing, marketing, promoting and sale of metal-on-metal hip implant devices.

6. The defendants, Biomet Orthopedics, LLC, Biomet Manufacturing Corp. and Biomet US Reconstruction, LLC, are all incorporated in the State of Indiana, in the United States, and are wholly owned subsidiaries of Biomet, Inc.

7. The defendant, Biomet Canada Inc., ("**Biomet Canada**") is incorporated in the province of Ontario and is a wholly owned subsidiary of the defendant, Biomet, Inc.

8. The defendants functioned as a joint enterprise for the research, design, manufacture, regulatory licensing, marketing, sale and post-market monitoring of their models of metal-on-metal hip implant devices. Biomet, Inc., Biomet Orthopedics, LLC, Biomet Manufacturing Corp., Biomet US Reconstruction, LLC and Biomet Canada Inc. are collectively referred to in this claim as "Biomet".

9. By virtue of the acts and omissions described herein, the defendants are liable in damages or other compensation to them and to the Class and that each defendant is responsible for the acts and omissions of the other defendant for the following reasons:

(a) each was the agent of the other;

(b) each company's business was operated so that it was inextricably interwoven with the business of the other;

(c) each company entered into a common advertising and business plan to research, design, test, manufacture, distribute, market and sell the Biomet Implants in Canada;

(d) the companies issued joint annual reports and consolidated financial statements, which included the statements of the Biomet group of companies and all of its wholly owned subsidiaries;

(e) the defendants shared certain executive officers and directors;

(f) the defendants had a common business plan and intended that their businesses be run as one global business organization; and

(g) they carried out the improper acts as pleaded below.

10. The defendants are joint tortfeasors. They each knew, or ought to have known, that the Biomet Implants were defective, and they each were in such a close and proximate relationship to the plaintiff and class members as to owe them a duty of care. They each could have taken reasonable steps to have prevented injury to the plaintiff and class members, including ensuring that the Biomet Implants were properly designed, tested and manufactured before marketing them, promptly recalling the Biomet Implants, and properly warning consumers of the risk of harm.

The Implanted Devices

11. The hip joint has a ball and cup structure comprising the femoral head, a ball-like structure at the top of the femur, which rotates within the acetabulum, a cup-like structure at the bottom of the pelvis. In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

12. Over time, age and wear break down the cartilage of the hip joint. In a diseased or otherwise damaged hip joint, the femur and acetabulum lack this necessary protection and begin to rub against each other, eventually grinding down the bones and causing significant pain, loss of function and immobility.

13. A diseased or otherwise damaged hip joint may be replaced by several means, including a total hip replacement or a hip resurfacing system.

14. A total hip replacement replaces the body's natural hip joint with an artificial one.

15. A typical total hip replacement system consists of four separate components:

(a) a femoral stem;

(b) a femoral head;

(c) an acetabular shell; and

(d) a liner.

16. During the implant surgery, the surgeon hollows out the patient's femur bone. A femoral stem is inserted into the patient's hollowed out femur with a metal ball, called the femoral head, attached at the top of the femoral stem. The femoral head forms the hip joint when it is placed inside a polyethylene liner and an acetabular shell or cup.

17. The Biomet Implants have been distributed in Canada since at least 1998 (in the case of the 38) and since 2004 (in the case of the Magnum and Recap Resurfacing device).

18. The Biomet Implants are classified as Class III devices under Health Canada's regulations, which are devices of substantial importance in preventing impairment of human health.

19. The Biomet Implants were developed in order to reconstruct human hip joints that are diseased or damaged due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture. The Biomet Implants are designed to replace all or parts of diseased or damaged hip joints in order to alleviate symptoms of these health conditions. Once implanted, the Biomet Implants were supposed to last for an average of 15 or more years. As described further below, the Biomet Implants were not properly

designed or manufactured such that they caused harm to the Class members and did not perform or last as required.

20. The Biomet Implants have a different design from typical hip implants. In the Biomet Implants: the metal femoral ball is placed directly in contact with a metal acetabular cup. Such implants are referred to as "Metal on Metal" or "MoM".

21. The Biomet Implants include total hip replacement and hip resurfacing systems. In a total hip replacement, the top of the femur is removed and replaced with an artificial stem and femoral ball.

22. Hip resurfacing is a surgical procedure that is an alternative to a total hip replacement procedure. In a hip resurfacing procedure, only the articular surface of the hip, being the acetabular cup and the femoral ball, is replaced. In contrast, a total hip replacement includes not only the acetabular cup and femoral ball, but also a femoral stem, which is implanted deep into the patient's femur and on which the femoral ball is affixed. Resurfacing implants are typically used in younger and/or more active individuals in order to preserve more of the hip bone.

The Plaintiff's Biomet Implants and Damages

23. Steven received a Magnum Biomet Implant (hip resurfacing) on May 31, 2006 in his left hip. Throughout 2007 and 2008 he suffered continuing and increasing pain, mobility difficulties and high metallosis. He needed to take pain medication and

was unable to work. He was forced to go on long term disability from his job with the Canadian federal government in 2007.

24. Steven required revision surgery to replace the metal-on-metal resurfacing device. On March 3, 2008 Steven's metal-on-metal resurfacing device was removed and replaced with a Magnum Biomet Implant total hip replacement. Following the revision surgery Steven continued to suffer hip pain and ongoing complications due to the faulty implant. He had trouble walking and continued to have metallosis. Steven was forced to continue to take pain medication simply to function and to get to sleep, and would wake up in pain. He was unable to work and remained on long term disability.

25. Ultimately, as a result of the faulty Biomet Implants which required him to remain on long term disability, Steven was forced to take early retirement from his job, and his pension was significantly reduced from what it should have been.

26. In 2012 Steven continued to have significant pain and serious mobility impairment, and his blood ion levels remained high.

27. Steven was required to undergo another hip revision surgery on March 15, 2013 to replace the metal-on-metal Biomet Implant with a non metal-on-metal implant from a different manufacturer .

28. Steven's second revision surgery in 2013 was extraordinarily difficult due to complications with his Biomet Implant. The surgery lasted approximately 5 hours (2

or 3 hours longer than is typical) and Steven suffered a much longer and more difficult recovery time than is typical as a result. He was bedridden for 2 months and forced to use a walker or crutches for 4 months afterward.

29. Steven remains on twice daily blood thinner shots because his 2013 revision surgery increased his risk of blood clots. Steven still takes high levels of Dilaudid for pain.

30. Steven's life has been severely compromised due to being implanted with the Biomet Implants. He has and continues to endure significant pain and suffering. He has been forced to take doses of Dilaudid, Diazapam and sleeping pills. His relationships with his family and friends have suffered due to his lack of mobility, his pain and his medications. His career was cut short and he has experienced anxiety, isolation and depression due to his inability to engage in his normal lifestyle. He will likely continue to require significant medical monitoring as a result of the Biomet Implants.

31. Steven's family and other Family Law Claimants have suffered and continue to suffer damages, including loss of income due to work absences required to attend to, care for and provide services to Class members, loss of care, guidance and companionship and expenses and special damages from loss of services formerly provided by Class members.

32. Steven was never warned of the risks associated with the use of the Biomet Implants. Had he been so advised he would have refused this medical product and insisted on a safer alternative treatment. But for the defendants' negligence and unlawful conduct he would not have suffered his injuries and incurred his damages.

33. The plaintiff claims that the Biomet devices failed due to design and manufacturing defects which resulted in excess metallic wear debris and which caused an adverse biological reaction, leading to the failure of the implant and the need to be replaced. The plaintiff alleges that Biomet knew or should have known that its metal-on-metal implant devices were not safe or effective, but failed to warn patients.

34. As a result of injuries caused by the failure of the two defective metal-on-metal hip implant devices and the consequent revision surgeries, the plaintiff has experienced significant pain and suffering, and loss of mobility and function. He has also suffered significant economic loss due to his forced early retirement. Finally, he has been put to significantly higher risk of future medical complications.

PROBLEMS WITH THE BIOMET IMPLANTS

35. The Biomet Implants were aggressively marketed by the defendants as having advantages over other hip replacement or resurfacing systems. In particular, the Biomet Implants were marketed as suitable, safe, effective, durable, hip replacements, as "high performance", long-lasting systems, as contributing to a better quality of life and as

being particularly suited for young, active patients, women and patients of smaller stature.

36. Furthermore, as reports mounted of adverse events with MoM hip implants manufactured by its competitors, Biomet aggressively marketed its MoM products as being safer than those of its competitors.

37. As further described below, the Biomet Implants were designed and manufactured improperly. These systems cause and have caused serious bodily injury and economic loss to the plaintiff and the Class. Biomet should not have sold or distributed the products in Canada given that they were designed and manufactured improperly, which was known or ought to have been known to all defendants involved variously in the design, manufacture and distribution of the Biomet Implants at the time they introduced the products into the marketplace. No proper warning was ever given by any of the defendants to the plaintiffs or the Class about the risks associated with the Biomet Implants.

38. On the contrary, Biomet aggressively promoted the device, stating that the Biomet Implants (a) would last much longer than other MoM and non-MoM implants, (b) were designed specifically to address the issue of wear debris, and (c) were the right choice for younger, active patients.

39. In or about the early 1990s, prior to the Biomet Implants being manufactured and distributed in Canada, several hip replacement devices with metal-on-metal design were shown to cause shedding of high levels of metallic ions, resulting in adverse biological reactions. At approximately the same time, scientific literature indicated that patients with metal-on-metal devices were developing pseudo-tumours at or near the site of implant. Previously, there had also been scientific research and literature demonstrating problems associated with metal-on-metal implant systems.

40. Shortly after the Biomet Implants were approved for sale in Canada, there were increasing reports of failures with the Biomet Implants, relating to, *inter alia*, premature loosening of the acetabular cup and other issues. These failures required premature revision surgeries to remove and replace the failed Biomet Implants.

41. Furthermore, Biomet was aware that the British Medicines and Healthcare Products Regulatory Agency (MHRA) and the US Food and Drug Administration expressed concern about MoM implants as early as 2006.

42. Revision rates for the Magnum were much higher than revision rates for non metal-on-metal hip implants.

43. Despite serious and numerous reports of failure of the Biomet Implants, no warning was provided to Canadian patients of the significant risk of failure of the Biomet Implants.

44. Biomet continues to market and distribute the Biomet Implants in Canada, despite unacceptably high early revision rates and other problems with the Biomet Implants.

DESIGN FLAWS IN THE BIOMET IMPLANTS

45. The Biomet Implants all shared common defective design characteristics that made them susceptible to early failure and cause serious adverse effects in patients. In particular the Biomet Implants used metal-on-metal components, which cause metal debris to be released into the surrounding tissue and other complications. The heavy metals released can be toxic, and may cause, *inter alia*, tissue necrosis, metallosis, pseudotumours, bone dislocation and failure of the hip joint.

46. The adverse effects experienced as a result of the Biomet Implants are painful and debilitating. Treatment may require removal of the implant, and its replacement with another device. Such revision surgery is problematic. Each time a patient is required to undergo a revision surgery there are increasing risks of complications. With each revision surgery, there is less bone for the surgeon to work with, and the chances of a satisfactory recovery are reduced. The Implant Patients were caused to require revision surgery more frequently and earlier in the lifespan of the implant than as compared to non metal-on-metal implants.

NEGLIGENCE

A. The Duties of Care

47. The defendants owed to the plaintiff and the Class a duty of care:

(a) to properly design, develop, test, manufacture, licence, assemble and distribute the Biomet Implants;

(b) to ensure the Biomet Implants were safe and free from defects prior to their distribution of them;

(c) to ensure that the Biomet Implants were fit for their intended or reasonably foreseeable use;

(d) not to use inappropriate materials to manufacture the Biomet Implants;

(e) to properly train their employees who were responsible for the design, testing, assembly and manufacturing of the Biomet Implants;

(f) to properly supervise their employees and consultants;

(g) to conduct adequate tests and clinical trials to determine the degree of risk associated with using the Biomet Implants prior to their manufacture, assembly and distribution;

(h) to monitor, investigate, evaluate and follow up on adverse reactions to the use of the Biomet Implants throughout the world;

(i) to warn the plaintiffs and the Class that the Biomet Implants carried a significant risk of premature component loosening, misalignment,

dislocation and fracture, and a significant risk of metal debris in the hip socket or related complaints, including metallosis and aseptic lymphocyte dominated vasculitis-associated lesion (commonly known as "ALVAL");

(j) to ensure that physicians and surgeons were kept fully and completely informed of all risks associated with using the Biomet Implants, including the excessive risk of premature failure, the excessive risk of contracting metallosis and ALVAL and the excessive risk that the implant would have to be replaced in significantly less than 15 years;

(k) to conduct ongoing clinical trials with long term follow up to determine the long term effects and risks of continued use of the Biomet Implants;

(l) to properly and promptly inform Health Canada and other regulatory agencies of the changing and increasing risks associated with using the Biomet Implants;

(m) to fix the defects in the Biomet Implants as soon as possible after they became aware of the defects and the injuries and risks associated with their use; and,

(n) to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage from the Biomet Implants.

48. The defendant Biomet Canada owed to the plaintiffs and the Class a duty of care:

(a) to properly label, market, distribute and sell the Biomet Implants and to ensure they were safe and free from defects prior to labelling, marketing, distributing and selling them;

(b) to ensure that the Biomet Implants were fit for their intended or reasonably foreseeable use prior to labelling, marketing, distributing and/or selling them;

(c) to properly supervise its employees and consultants;

(d) to monitor, investigate, evaluate and follow up on adverse reactions to the use of the Biomet Implants throughout the world;

(e) to warn the plaintiffs and the Class that the Biomet Implants carried a significant risk of premature component loosening, misalignment, dislocation and fracture, and a significant risk of metal debris in the hip socket or related complaints, including metallosis and aseptic lymphocyte dominated vasculitis-associated lesion (commonly known as "ALVAL");

(f) to ensure that physicians and surgeons were kept fully and completely informed of all risks associated with using the Biomet Implants, including the excessive risk of premature failure, the excessive risk of contracting metallosis and ALVAL and the excessive risk that the implant would have to be replaced in significantly less than 15 years;

(g) to properly and promptly inform Health Canada and other regulatory agencies of the changing and increasing risks associated with using the Biomet Implants; and

(h) to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage from the Biomet Implants.

B. The Breaches

(i) Defective Design

49. The defendants breached their duty of care to the plaintiffs and the Class as described above with respect to the design of the Biomet Implants as follows:

(a) they improperly designed the Biomet Implants, causing them to fail well before the natural life cycle of non metal-on-metal hip implants;

(b) they failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine whether the design of the Biomet Implants was defective, thereby increasing the risks of injury and harm associated with the use of the Biomet Implants;

(c) they were aware or ought to have been aware that the Biomet Implants were unfit and defective and ought not to have been introduced into the market place;

(d) they failed to provide proper long term investigations of the effects and risks of continued use of the Biomet Implants; and

(e) they failed to fix the defects in the Biomet Implants or to withdraw the Biomet Implants from the marketplace as soon as possible after they

became aware of the defects and the injuries and risks associated with their use.

(ii) Defective Manufacturing

50. The defendants breached their duty of care to the plaintiffs and the Class as described above with respect to the manufacturing and assembly of the Biomet Implants as follows:

(a) they failed to assemble and manufacture the Biomet Implants so they would operate safely and effectively without exposing their consumers to undue risks;

(b) they used inappropriate materials to manufacture the Biomet Implants;

(c) they failed to properly train their employees who were responsible for the assembly and manufacturing of the Biomet Implants; and

(d) they failed to properly supervise their employees and consultants involved in the assembly and manufacture of the Biomet Implants.

(iii) Failure to Warn

51. The defendants breached their duty of care to the plaintiffs and the Class as described above with respect to their duty to warn of the defects in the design and manufacture of the Biomet Implants as follows:

(a) they failed to properly label, distribute, market and sell the Biomet Implants and failed to ensure they were safe and free from defects prior to selling or distributing them;

(b) they failed to ensure that the Biomet Implants were fit for their intended or reasonably foreseeable use prior to labelling, marketing, distributing and selling them;

(c) they failed to properly supervise their employees and consultants involved in labelling, marketing, distributing and selling them;

(d) they were aware or ought to have been aware that the Biomet Implants were unfit and defective and ought not to have been introduced into the market place;

(e) they labelled, marketed, distributed and sold the Biomet Implants without adequately disclosing the risks associated with using the Biomet Implants;

(f) they failed to give Health Canada complete and accurate information concerning the Biomet Implants by failing to disclose the problems with the Biomet Implants on a timely basis or at all;

(g) they failed to adequately warn the plaintiffs, the Class and their physicians and surgeons of the risks then known or which were reasonably foreseeable in using the Biomet Implants;

(h) with full knowledge that the Biomet Implants posed significant risk of premature failure, of contracting metallosis and ALVAL and that the

implants would have to be replaced in significantly less than 15 years, they failed to warn the plaintiffs and the Class and instead continued to sell, market and distribute the Biomet Implants throughout Canada;

(i) they failed to warn the Class and their physicians and surgeons about the need for comprehensive regular medical monitoring to ensure early discovery of complications from the use of the Biomet Implants set out above;

(j) they failed to adequately monitor, evaluate and act promptly upon adverse reactions and high revision rates in Biomet Implants in Canada and throughout the world;

(k) they failed to establish any adequate procedures to educate their sales representatives respecting the risks associated with the Biomet Implants;

(l) in particular, they continued to distribute and sell the Biomet Implants notwithstanding that the FDA and Health Canada had received numerous complaints involving patients with Biomet Implants; and

(m) they failed to provide clear and proper instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damage from the Biomet Implants.

52. The defects and risks associated with the Biomet Implants were in the defendants' exclusive knowledge and control. The extent of the defects and risks was not known and could not have been known to the plaintiffs or the Class. The injuries of the

plaintiffs and the Class would not have occurred but for the negligence of the defendants in failing to ensure that the Biomet Implants were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with the Biomet Implants to the plaintiffs, the Class and to their physicians.

53. The defendants were aware or ought to have been aware of the high degree of complication and failure rates associated with Biomet Implants from the outset or at least long before the FDA warned against further use of metal-on-metal hip implants in 2012.

54. The defendants were aware or ought to have been aware of the defect in manufacture and design from the outset or at least well prior to the FDA warning issued against further use of metal-on-metal hip implants in 2012. Nevertheless they continued to market and distribute the Biomet Implants in Canada.

C. Causation

55. The plaintiffs plead that they and the other Class members would not have had the Biomet Implants implanted had the defendants not acted negligently. There were safer, economically feasible alternative implants available in the marketplace. The propensity of the Biomet Implants to injure those who were implanted far outweighed any value to their use. In fact, there was no value to their use.

D. Damages

56. The plaintiffs and the Class have suffered and will continue to suffer damages as a direct result of the defendants' negligence including, but not limited to, damages for personal injuries, mental anguish, pain and suffering, loss of employment income and benefits, loss of enjoyment of life, possibly death, and special damages and expenses.

57. Members of the Class who do not require revision surgeries to remove their Biomet Implants will nonetheless suffer damages from the cost of additional monitoring of their Biomet Implants including but not limited to frequent physician visits, blood tests, diagnostic imaging and will suffer psychiatric and psychological injuries as well.

58. As a result of the defendants' conduct described above, the plaintiffs and other Class members have suffered damages and losses, including, but not limited to:

(a) enduring or having to endure painful medical procedures to implant the Biomet Implants;

(b) enduring or having to endure painful medical procedures to explant the Biomet Implants;

(c) enduring painful medical procedures to implant new hip replacement systems that are free of defects;

(d) personal injury, including immobility, pain, inflammation, swelling, scarring, pseudo-tumours and other adverse effects and complications associated with the Biomet Implants and the adverse effects of the diseases which necessitated the implant of the Biomet Implants in the first place;

(e) severe emotional distress related to the pain and suffering associated with defective Biomet Implants;

(f) the risk of death or other serious injuries;

(g) costs associated with replacing the Biomet Implants;

(h) costs associated with monitoring the Biomet Implants;

(i) out-of-pocket expenses incurred by the Class members or for their benefit; and

(j) loss of income.

59. The plaintiffs and the other Class Members have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring and/or medications.

60. As a result of the defendants' conduct described above, the Family Law Claimants have suffered damages, including, but not limited to:

(a) actual expenses reasonably incurred for the benefit of Class Members;

(b) travelling expenses incurred while visiting Class Members during treatment or recovery;

(c) loss of income or the value of services provided for Class Members where services, including nursing and housekeeping, have been provided; and,

(d) compensation for loss of support, guidance, care and companionship that they might reasonably have expected to receive from Class Members.

61. All relevant provincial and territorial health insurers have incurred expenses with respect to the purchase of the Biomet Implants and the medical treatment of the plaintiffs and the Class as a result of the defendants' negligence. Consequently, the health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their direct right of action or right of subrogation in respect of all past and future insured services. This action is maintained on behalf of all provincial and territorial health insurers. The plaintiffs plead and rely upon the statutes listed in paragraph 68.

62. The above described damages were foreseeable as a result of the defendants' actions.

PUNITIVE DAMAGES

63. The plaintiffs claim punitive damages in the sum of ten million dollars as a result of the egregious, outrageous and unlawful conduct of the defendants and, in particular, their callous disregard for the health and lives of vulnerable patients in

Canada. In particular, the defendants' conduct in continuing to manufacture and/or market, sell and distribute the Biomet Implants after obtaining knowledge they were failing and not performing as represented and intended showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages in a sum which will serve to deter the defendants from similar conduct in the future.

64. The defendants committed various independent actionable wrongs including:

(a) minimizing and understating the risks associated with the Biomet Implants;

(b) positively promoting and marketing the Biomet Implants while withholding relevant information about the risks as set out above; and

(c) failing to disclose the risks to the Class members and to regulatory authorities, including the FDA and Health Canada.

65. The plaintiffs plead and rely upon the *Class Proceedings Act, 1992,* S.O. 1992, c. 6, the *Food and Drugs Act*, R.S.C. 1985, c. F.27 and regulations thereunder, the *Family Law Act*, R.S.O. 1990, c. F.3, and all similar provincial legislation as listed in Schedule "A" and the Medical Devices Regulation, SOR/98-282.

REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

66. The plaintiffs plead that this action has a real and substantial connection with Ontario because, among other things:

(a) the defendants distribute and sell their products in Ontario and derive substantial revenue from such sales;

(b) the defendant, Biomet Canada Inc.'s head office is in Oakville, Ontario;

(c) the application to Health Canada for permission to market the Biomet Implants in Canada was made in Ottawa, Ontario;

(d) the defendants advertised their products, including the Biomet Implants, in Ontario;

(e) the trademarks for the Magnum and 38 were registered with the Canadian Intellectual Property Office in Ottawa;

(f) the defendants hold the licence to patents for the Biomet Implants which patents are registered with the Canadian Intellectual Property Office in Ottawa;

(g) the tort was committed in the province;

(h) the plaintiffs and other class members were implanted with their Biomet Implants and sustained consequent damages in Ontario; and

(i) the defendants, are necessary and proper parties to the action.

67. The plaintiffs plead and rely on s. 17.02(g), (h), (o) and (p) of the Rules of Civil Procedure permitting service outside Ontario in respect of the foreign defendants.

68. The plaintiff pleads and relies upon the following health care statutes with respect to those subrogated claims of Class members:

(a) *Health Insurance Act*, R.S.O. 1990, c. 11-6;

(b) *Health Care Cost Recovery Act*, S.B.C. 2008, c.27

(c) *Alberta Health Care Insurance Act*, R.S.A. 200, c.A-20;

(d) *Hospitals Act*, R.S.A. 2000, c. 11;

(e) *Department of Health Act*, R.S.S. 1978, D-17;

(f) *Health Services Insurance Act*, C.C.S.M., C.1135;

(g) *Hospital Services Act*, R.S.N.B. 1973, c.11-9

(h) *Health Services and Insurance Act*, R.S.N.S. 1989, c.197;

(i) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;

(j) *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7

(k) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c.T-3; and

(l) *Hospital Insurance Services Act*, R.S.Y. 2002, c.112.

November 4, 2013

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SCHEDULE "A"
PROVINCIAL STATUTES RE FAMILY MEMBER CLAIMS

ALBERTA

Tort-feasors Act, R.S.A. 2000 c. T-5

Loss of consortium through injury

2.1(1) When a person has, either intentionally or by neglect of some duty existing independently of contract, inflicted physical harm on a married person and thereby deprived the spouse of that married person of the society and comfort of that married person, the person who inflicted the physical harm is liable in an action for damages by the spouse or in respect of the deprivation.

2.1(2) The right of a spouse to bring the action referred to in subsection (1) is in addition to, and independent of, any right of action that the married person has, or any action that the spouse in the name of the married person has, for injury inflicted on the married person.

The Domestic Relations Act, R.S.A. 2000, c. D 10.5, was repealed by RSA 2003, c.F-4.5 [Family Law Act].

In addition the following Act applies:

Fatal Accidents Act , R.S.A. 2000, c. F-8,

2. Action for damages. When the death of a person has been caused by a wrongful act, neglect or default that would, if death had not ensued, have entitled the injured party to maintain an action and recover damages, in each case the person who would have been liable if death had not ensued is liable to an action for damages notwithstanding the death of the party injured.

Persons entitled to benefits

3(1)An action under this Act

(a) shall be for the benefit of the spouse, adult interdependent partner, parent, child, brother or sister of the person whose death has been so caused, and

(b) shall be brought by and in the name of the executor or administrator of the person deceased,

and in the action the court may give to the persons respectively for whose benefit the action has been brought those damages that the court considers appropriate to the injury resulting from the death.

3(2) If there is no executor or administrator, or if the executor or administrator does not bring the action within one year after the death of the party injured, then the action may be brought by and in the name of all or any of the persons for whose benefit the action would have been, if it had been brought by or in the name of the executor or administrator.

3(3) Every action so brought shall be for the benefit of the same persons and is as nearly as possible subject to the same regulations and procedure as if it were brought by and in the name of the executor or administrator.

Damages for bereavement

8(1) In this section,

(a) "child" means a son or daughter, whether legitimate or illegitimate;

(b) "parent" means a mother or father.

8(2) If an action is brought under this Act, the court, without reference to any other damages that may be awarded and without evidence of damage, shall award damages for grief and loss of the guidance, care and companionship of the deceased person of

> (a) subject to subsections (3) and (4), $75 000 to the spouse or adult interdependent partner of the deceased person,
>
> (b) $75 000 to the parent or parents of the deceased person if the deceased person, at the time of death,
>
> > (i) was a minor, or
> >
> > (ii) was not a minor but was unmarried and had no adult interdependent partner, to be divided equally if the action is brought for the benefit of both parents, and
>
> (c) $45 000 to each child of the deceased person who, at the time of the death of the deceased person,
>
> > (i) is a minor, or
> >
> > (ii) is not a minor but is unmarried and has no adult interdependent partner.

8(3) The court shall not award damages under subsection (2)(a) to the spouse or adult interdependent partner if the spouse or adult interdependent partner was living separate and apart from the deceased person at the time of death.

8(4) [Repealed 2002, c. A-4.5, s. 36(5)(c).]

8(5) A cause of action conferred on a person by subsection (2) does not, on the death of that person, survive for the benefit of the person's estate.

MANITOBA

Fatal Accidents Act, C.C.S.M. c. F50, as amended

Similarly applicable to spouses, children and other defined family members only upon death of benefactor.

NEW BRUNSWICK

Fatal Accidents Act, R.S.N.B. 1973, c.F-7

Similarly applicable to spouses, children and other defined family members only upon death of benefactor.

NEWFOUNDLAND

Fatal Accidents Act, R.S.N.L. 1990, c.F-6

Similarly applicable to spouses, children and other defined family members only upon death of benefactor.

NOVA SCOTIA

Fatal Injuries Act, R.S.N.S. 1989, c.163, amended 2000 c.29, ss9-12

Similarly applicable to spouses, children and other defined family members only upon death of benefactor.

ONTARIO

Family Law Act, R.S.O. 1990, c. F.3

Right of dependants to sue in tort
61. (1) If a person is injured or killed by the fault or neglect of another under circumstances where the person is entitled to recover damages, or would have been entitled if not killed, the spouse, as defined in Part III (Support Obligations), children, grandchildren, parents, grandparents, brothers and sisters of the person are entitled to recover their pecuniary loss resulting from the injury or death from the person from whom the person injured or killed is entitled to recover or would have been entitled if not killed, and to maintain an action for the purpose in a court of competent jurisdiction. R.S.O. 1990, c. F.3, s. 61 (1); 1999, c. 6, s. 25 (25); 2005, c. 5, s. 27 (28).

Damages in case of injury
(2) The damages recoverable in a claim under subsection (1) may include,
(a) actual expenses reasonably incurred for the benefit of the person injured or killed;
(b) actual funeral expenses reasonably incurred;
(c) a reasonable allowance for travel expenses actually incurred in visiting the person during his or her treatment or recovery;
(d) where, as a result of the injury, the claimant provides nursing, housekeeping or other services for the person, a reasonable allowance for loss of income or the value of the services; and
(e) an amount to compensate for the loss of guidance, care and companionship that the claimant might reasonably have expected to receive from the person if the injury or death had not occurred. R.S.O. 1990, c. F.3, s. 61 (2).

PEI

Fatal Accidents Act, R.S.P.E.I 1988, c.F-5, as amended

Similarly applicable to spouses, children and other defined family members only upon death of benefactor.

QUÉBEC

Civil Code of Québec (S.Q. 1991, c. 64), Articles 454, 1457, 1607, 1609, 1614, 1615, 1616, 2926 and 2930.

SASKATCHEWAN

Fatal Accidents Act, R.S.S. 1978, c.F-11 as amended

Similarly applicable to spouses, children and other defined family members only upon death of benefactor.

STEVEN DALTON DINE
Plaintiff

-and-

BIOMET, INC. and others
Defendants

Court File No.

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED AT TORONTO

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